



DEPARTMENT OF HEALTH & HUMAN SERVICES

G4310d

Public Health Service  
Food and Drug Administration

Southwest Import District  
4040 N. Central Expressway  
Dallas, Texas 75204

## WARNING LETTER

September 17, 2003

Ref: FY03-SWID-015

### VIA FEDEX MAIL

Mr. Rodolfo Fonseca, President  
Formar Import and Export, Inc.  
761 Terminal Street  
Building 1

Los Angeles, CA 90021-1112

**Reference:** Customs Entry No. 965-0083656-2 and 965-0085162-9  
**Product:** Dried Chili Peppers

Dear Mr. Fonseca:

On September 17, 2002 and December 20, 2002 your firm offered for import into the United States [REDACTED] sacks of dried chilies under customs entry 965-0083656-2 and 675 sacks and [REDACTED] boxes of dried peppers under customs entry 965-0085162-9, respectively. On September 20, 2002 and on December 23, 2002, the U.S. Food and Drug Administration (FDA) notified your firm that the peppers were subject to detention without physical examination based on a past history of filth and mold contamination. Your firm submitted no information to overcome the appearance of this violation and the entries were subsequently refused admission On January 15, 2003 and April 29, 2003.

Section 801(a) of the Federal Food, Drug, and Cosmetic Act ("Act") directs the Secretary of the Treasury to issue a Notice of Refusal when it appears from

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examination of samples, or otherwise, that an imported shipment is in violation. This Section also orders the destruction of any such shipment refused admission, unless it is exported within 90 days of the date of the notice, or within such additional time as may be permitted pursuant to such regulations. Under the Act, the product under entries 965-0083656-2 and 965-0085162-9 are subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to contain filth, which is in violation of Section 402(a)(3).

On January 1, 2003, FDA documented the substitution of the refused product upon examination of the merchandise at the Otay Mesa Commercial Port of entry in San Diego California. Under entry 965-0083656-2, the peppers offered for importation were dried Anaheim peppers. The peppers that were redelivered for exportation and which were examined by FDA Investigators were Arbor peppers. FDA again documented the substitution of the refused product upon examination of the merchandise at the Otay Mesa Commercial Port of entry in San Diego California. Under entry 965-0085162-9 the peppers offered for importation were dried Ancho peppers. The peppers that were redelivered for exportation and which were examined by FDA Investigators were boxes of dried de Arbol peppers. In addition the labels of sacks of peppers appeared different and were attached by staples rather than tape as per the original entry.

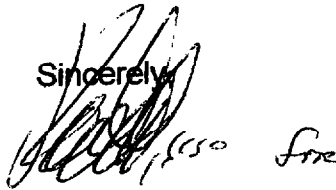
This is a violation of Title 21, Code of Federal Regulations, Section 1.90, which requires the importer to hold an entry intact pending receipt of a May Proceed or Release Notice from FDA

It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug and Cosmetic Act, and the regulations promulgated there under. Failure to prevent future violations may result in regulatory action without further notice such as seizure, injunction, or detention without examination of future shipments. Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation. Your written reply should be addressed to the Food and Drug Administration, Attention: Brian Ravitch, Compliance Officer, 2320 Paseo De Las Americas, Suite 200, San Diego California 92154.

We also wish to remind you that making fraudulent misrepresentations or false statements to federal officials are criminal offences under Title 18, United States Code (18 USC), 542 and 1001. When evidence demonstrates the article presented to FDA for examination is not from the original entry, but was substituted for the entry, the article may be seized under Title 19 section 1595a (c). Liquidated damages may also be assessed for articles not redelivered. Criminal charges of entry contrary to law (18 USC 545) may result in addition to the charges mentioned above. Criminal offenses can result in imprisonment or fines or both.

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Sincerely,

A handwritten signature in dark ink, appearing to read "R. J. Deininger", is written over the word "Sincerely,".

Robert J. Deininger  
Director, Southwest Import District